Out-of-Bounds:

Rising Prescription Drug Prices for Seniors

A REPORT BY

Families USA

Out-of-Bounds: Rising Prescription Drug Prices for Seniors

Families USA Publication No. 03-106 © 2003 by Families USA Foundation

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This publication is available online at (www.familiesusa.org).

INTRODUCTION

rescription drug expenditures in 2002 continued to be one of the fastest growing components of health care spending, disproportionately contributing to overall increases in health care costs.¹ Three factors fuel this growth:

- more drugs are being prescribed;
- new, higher-priced drugs are prescribed more frequently; and
- the cost of drugs is rising—so much so, in fact, that approximately onethird of increased drug spending is attributed to rising drug prices.²

Rising prices affect everyone who purchases prescription drugs—employers, insurers, states (which buy drugs for Medicaid beneficiaries and state employees), and, of course, consumers in general. The impact of rising drug prices is particularly harsh on older Americans, who disproportionately rely on prescription drugs and, because Medicare still lacks a drug benefit, disproportionately go without drug coverage.

It is estimated that approximately one-third of Medicare beneficiaries have no drug coverage at all; nearly 20 percent more are estimated to have coverage for only part of the year.³ They must pay out of their own pockets for all or part of the cost of the prescription drugs they use. This is a dramatically increasing burden: The total spending of senior citizens on prescription drugs rose an estimated 44 percent from 2000 to 2003.⁴ Moreover, many seniors live on fixed incomes that rise in pace with inflation; if the prices they pay for drugs consistently grow faster than inflation, their prescription drug costs will consume a growing portion of their finances every year.

Recognizing that seniors are disproportionately affected by rising drug prices, since 1999 Families USA has monitored the prices of the 50 prescription drugs most commonly prescribed to older Americans. Year after year, our findings have shown that the costs of these 50 drugs have risen faster than the rate of inflation.⁵ This year's study, the latest in our series of reports on prescription drug prices, is no exception. The cost of these 50 drugs increased nearly three-and-a-half times the rate of inflation from January 2002 to January 2003, compared to just under three times inflation in the previous year.

FINDINGS

The prices of the 50 prescription drugs most frequently used by the elderly rose 3.4 times the rate of inflation in 2002. On average, the cost of these top 50 drugs increased 6.0 percent from January 2002 to January 2003, while the rate of inflation, excluding energy, was 1.8 percent during that same period (Table 1).

Of these 50 drugs:

- One-fourth (12 of 50) did not increase in price.
- Nearly three-quarters (37 of 50) rose in price one and one-half or more times the rate of inflation.
- More than half (27 of 50) rose in price three or more times the rate of inflation.

Drugs with Fastest-Growing Prices in 2002

Among the 50 drugs most frequently used by seniors with the fastest-rising prices, eight increased more than 15 percent from January 2002 to January 2003:

- Claritin, a non-sedating antihistamine marketed by Schering, rose 21.1 percent, nearly twelve times the rate of inflation.
- Klor-Con 10, a potassium replacement marketed by Upsher-Smith, rose 19.7 percent, more than eleven times the rate of inflation.
- Miacalcin, an osteoporosis treatment marketed by Novartis, rose 18 percent, more than ten times the rate of inflation.
- Premarin, an estrogen replacement marketed by Wyeth-Ayerst, rose
 17.5 percent, nearly ten times the rate of inflation.
- Atenolol (25 mg), a generic beta-blocker manufactured by Geneva, rose
 16.4 percent, more than nine times the rate of inflation.
- Toprol XL (both strengths), a beta-blocker indicated for angina, hypertension, and heart failure marketed by Astra-Zeneca, rose more than 16 percent, over nine times the rate of inflation.

- Combivent, marketed by Boehringer Ingelheim and used to treat chronic asthma and other serious respiratory conditions, rose 15 percent, eight and one-half times the rate of inflation.
- The price of 19 other drugs increased three or more times the rate of inflation: Fosamax, used to treat osteoporosis; Plavix, for reducing the risk of heart attack or stroke; Zocor (20 and 40 mg), Pravachol, and Lipitor (20 mg), for lowering cholesterol; Xalatan, for glaucoma; Lanoxin (both strengths), for heart failure; Synthroid (all dosages), a synthetic thyroid hormone supplement; Protonix, for gastric reflux; Cozaar, for hypertension; Evista, for osteoporosis; atenolol (50 mg), a beta-blocker; Celexa, an antidepressant; Glucotrol XL, for diabetes; and Diovan, for hypertension.

Drugs with the Fastest-Growing Prices over the Past Five Years

Of the 50 drugs most frequently used by seniors, 38 have been on the market since January 1998. From January 1998 to January 2003, the prices of these 38 drugs increased an average of 29.2 percent—nearly two and one-half times the rate of inflation for the same period, which was 11.8 percent (Table 2).

Of these 38 drugs:

- The prices of 32 (roughly four out of five) rose more than one and one-half times the rate of inflation during this five-year period.
- More than three-quarters of these drugs (29 of 38) rose in price two or more times the rate of inflation.
- Over one-third of these drugs (13 of 38) increased in price four or more times the rate of inflation.

Among these 38 prescription drugs, the following showed the most significant price increases from January 1998 to January 2003:

- Hydrochlorothiazide, a generic thiazide diuretic manufactured by Zenith, rose 360.5 percent, over thirty times the rate of inflation.
- Furosemide (20 mg and 40 mg), generic loop diuretics manufactured by Mylan, rose 136.4 percent and 135.2 percent, respectively.

- Premarin, an estrogen replacement, rose 88.5 percent, seven and one-half times the rate of inflation.
- Potassium chloride, a generic potassium replacement, rose 81.5 percent, nearly seven times the rate of inflation.
- Klor-Con 10, a potassium replacement, rose 72.1 percent, more than six times the rate of inflation.
- Three strengths of Synthroid, a synthetic thyroid agent, each rose over63 percent, more than five times the rate of inflation.
- Combivent, used to treat chronic asthma and other serious respiratory conditions, rose 54 percent, more than four and one-half times the rate of inflation.
- Claritin, a popular allergy medication, rose 51.2 percent, more than four times the rate of inflation.

Generic Drugs vs. Brand-Name Drugs

Between January 2002 and January 2003, 15 of the 50 prescription drugs most frequently used by seniors (30 percent) were generic drugs, with the remaining 35 being brand-name products. On average, the generic drugs increased in price much less rapidly than the brands and had significantly lower average annual costs (see Figure 1).

- Nine of these 15 generic drugs (60 percent) saw no price increase between January 2002 and January 2003. The generics that did increase in price were Klor-Con 10 (10 meq), which rose 19.7 percent, more than eleven times the rate of inflation; atenolol (25 mg and 50 mg), which rose 16.4 percent and 12.8 percent, respectively; Digitek and potassium chloride, which both increased 5 percent, or nearly three times the rate of inflation; and Klor-Con M20 (20 meq), which rose 4.6 percent.
- By contrast, only three brand-name drugs—Prilosec, from Astra-Zeneca (for gastric reflux); Norvasc, from Pfizer (a calcium channel blocker); and Paxil, from GlaxoSmithKline (an antidepressant)—did not increase in price from January 2002 to January 2003.

■ From January 2002 to January 2003, the average annual cost of the 15 generic drugs increased much more slowly than the average annual cost of the brand-name drugs. Average annual cost for the generics rose from \$348 to \$357 while the average annual price for the brands increased from \$1,399 to \$1,498—an increase of 2.6 percent for generics compared to 7.1 percent for brands, or a \$9 per year average increase for generic drugs compared to a \$99 increase for the brandname drugs.

Figure 1
Annual Wholesale Cost for Drugs Used by the Elderly: 1996-2003*



^{*} Annual wholesale cost of drug therapy on January 15 each year for top 50 drugs (weighted by expenditures for each drug) based on usual daily dose as found in PriceChek PC.

Of these 15 generic drugs, 11 were on the market for the five-year period from January 1998 to January 2003.

- One did not increase in price.
- The prices of four rose at or slightly above the rate of inflation.
- The prices of two rose between six and seven times inflation.
- The prices of four rose ten or more times the rate of inflation. These were: three strengths of furosemide, each of which increased over eleven times the rate of inflation; and hydrochlorothiazide, a thiazide diuretic, which increased more than thirty times the rate of inflation. The average five-year increase in the annual wholesale price for these four drugs was \$29.75.

High-Cost Drugs

Of the 50 drugs used most frequently by seniors, the average annual cost as of January 2003 was \$1,439 (Table 3). The top five drugs most frequently prescribed to the elderly were brand-name drugs. All five had annual costs that exceeded \$500. For two, the annual cost exceeded \$1,500 per year.

The frequently prescribed drugs with the highest annual cost as of January 2003 were all brand-name drugs. These included:

- Combivent, marketed by Boehringer Ingelheim to treat chronic asthma and other serious respiratory conditions: \$10,868 annual cost.
- Miacalcin, marketed by Novartis to treat osteoporosis: \$7,132 annual cost.
- Celebrex, an anti-inflamatory/analgesic marketed by Pfizer: \$2,102 annual cost.
- Prilosec, Prevacid, and Nexium, all for gastric reflux: \$1,684, \$1,690, and \$1,614 annual cost, respectively.
- Zocor (20 and 40 mg), a lipid-lowering agent marketed by Merck:
 \$1,674 annual cost for both strengths.

By contrast, none of the 15 generics had an annual cost of more than \$500. The generics with the highest annual costs as of January 2003 were:

- Isosorbide mononitrate (60 and 30 mg), manufactured by Warrick and used to treat angina: \$429 and \$407 annual cost, respectively.
- Metoprolol tartrate (a beta blocker that appears twice among the top 50 drugs, each time from a different manufacturer, both at the same price): \$405 annual cost.
- Klor-Con 10 (10 meq), a potassium replacement manufactured by Upsher-Smith: \$386 annual cost.

Frequent Price Changes

Of the 38 drugs on the market for the five-year period from January 1998 to January 2003, 25 drugs—66 percent—had at least five price changes during this period (Table 3). Prices jumped 10 or more times during this period for five of these drugs:

- Claritin, an antihistamine from Schering: 13 price changes and an overall increase of more than 50 percent.
- Synthroid (all three dosages in the top 50), a synthetic thyroid agent marketed by Abbott: 10 price changes and an overall increase of more than 60 percent.
- Premarin, an estrogen replacement marketed by Wyeth-Ayerst: 10 price changes and an overall increase of nearly 90 percent.

NOTES TO TABLES

Drug names that are capitalized are brand names. The drugs that are not capitalized are generic, with the exception of the generic HCTZ/ triamterene. Three drugs—Klor-Con M20, Klor-Con 10, and Digitek—are branded versions of off-patent drugs. Because these are not the innovator drug, or the first brand, they are counted as generics.

The following are abbreviations used in the tables and the explanations of each:

NDA New Drug Application

mg milligram, which is 1/1,000th of a gram

mg/ac milligrams per actuation (spray)

mcg microgram, which is 1/1-millionth of a gram

meq milliequivalent, an alternate form of measurement

IU International Unit, a measurement of biological activity

IU/ac International Units per actuation (spray)

sol solution

inj injection

tab tablet

tab cr controlled release tablet

tab er extended release tablet

cap capsule

cap cr controlled release capsule

ophth sol ophthalmologic solution

Table 1
Annual Percent Change in Price of the Top 50 Drugs (by Number of Claims) Used by the Elderly^a

Rank by # of Claims	Drug Name		Stren	gth	Dose Form	Marketer	NDA Approval Date	02-03 % Price Change	02-03 Multiple of CPI
1	Lipitor		10	mg	tab	Pfizer	Dec-96	3.3%	1.9
2	Norvasc		5	mg	tab	Pfizer	Jul-92	3.6%	2.0
3	Fosamax		70	mg	tab	Merck	Sep-95	5.9%	3.3
4	Plavix		75	mg	tab	Bristol-Myers Squibb	Nov-97	6.9%	3.9
5	Prilosec		20	mg	cap cr	Astra Zeneca	Sep-89	0.0%	0.0
6	Celebrex		200	mg	cap	Pfizer	Dec-98	4.6%	2.6
7	furosemide	b	40	mg	tab	Mylan	Aug-81	0.0%	0.0
8	Zocor		20	mg	tab	Merck	Dec-91	10.1%	5.7
9	Prevacid		30	mg	cap cr	TAP Pharm	May-95	3.9%	2.2
10	Norvasc		10	mg	tab	Pfizer	Jul-92	0.0%	0.0
11	Lipitor	ı.	20	mg	tab	Pfizer	Dec-96	8.0%	4.5
12 13	Klor-Con M20	b	20	meq	tab cr	Upsher-Smith	Nov-98	4.6%	2.6 9.2
13	Toprol XL Xalatan		50 0.005	mg %	tab cr sol	Astra Zeneca Pfizer	Jan-92 Jun-96	16.3% 5.9%	3.3
15	Vioxx		25		tab	Merck	May-99	4.5%	2.5
16	Lanoxin	Ь	0.125	mg mg	tab	Merck GlaxoSmithKline	May-99 Sep-97	4.5% 8.3%	2.5 4.7
17	Synthroid	Ь	0.123	mg	tab	Abbott	Dec-63	6.7%	3.8
18	Synthroid	Ь	0.05	mg	tab	Abbott	Dec-63	6.8%	3.8
19	metoprolol tartrate	Ь	50	mg	tab	Mylan	Dec-93	0.0%	0.0
20	isosorbide mononitrate	b	30	mg	tab cr	Warrick	Sep-98	0.0%	0.0
21	Digitek	b	0.125	mg	tab	Bertek	Mar-95	5.0%	2.8
22	isosorbide mononitrate	b	60	mg	tab cr	Warrick	Sep-98	0.0%	0.0
23	metoprolol tartrate	b	50	mg	tab	Teva	Jan-95	0.0%	0.0
24	Synthroid	Ь	0.075	mg	tab	Abbott	Dec-63	6.7%	3.8
25	Zoloft		50	mg	tab	Pfizer	Dec-91	5.0%	2.8
26	Protonix		40	mg	tab	Wyeth	Feb-00	12.2%	6.8
27	Cozaar		50	mg	tab	Merck	Apr-95	5.9%	3.3
28	atenolol	b	25	mg	tab	Geneva	Sep-91	16.4%	9.2
29	Premarin		0.625	mg	tab	Wyeth-Ayerst	May-64	17.5%	9.8
30	furosemide	b	20	mg	tab	Mylan	Aug-81	0.0%	0.0
31	Zocor		40	mg	tab	Merck	Dec-03	10.1%	5.7
32	Evista		60	mg	tab	Lilly	Dec-97	5.5%	3.1
33	Nexium		40	mg	cap	Astra Zeneca	Feb-01	2.4%	1.4
34	Zocor		10	mg	tab .	Merck	Dec-91	4.0%	2.2
35	Combivent		1	mg	aerosol	Boehringer Ingelheim	Oct-96	15.0%	8.5
36	Miacalcin		200	IU/act	spray	Novartis	Aug-95	18.0%	10.1
37	atenolol	b	50	mg	tab	Geneva	Sep-91	12.8%	7.2
38 39	Pravachol Paxil		20	mg	tab tab	Bristol-Myers Squibb GlaxoSmithKline	Oct-91 Dec-92	10.8%	6.1
39 40			20 100	mg	tab tab cr	Astra Zeneca	Dec-92 Jan-92	0.0% 16.4%	0.0 9.2
41	Toprol XL Celexa		20	mg	tab cr	Forest	Apr-00	7.3%	4.1
42	hydrochlorothiazide	Ь	25	mg	tab	Zenith (Ivax)	Apr-00 Jun-98	0.0%	0.0
43	Glucotrol XL	D	10	mg mg	tab cr	Pfizer	Apr-94	12.7%	7.1
44	Klor-Con 10	b		meq	tab cr	Upsher-Smith	Nov-98	19.7%	11.1
45	furosemide	Ь	40	mg	tab	Geneva	Aug-81	0.0%	0.0
46	potassium chloride	b	10	-	cap cr	Ethex	Feb-8 <i>7</i>	5.0%	2.8
47	Lanoxin	b	0.25	mg	tab	GlaxoSmithKline	Aug-67	8.3%	4.7
48	Claritin		10	mg	tab	Schering	Apr-93	21.1%	11.9
49	Diovan		80	mg	tab	Novartis	Jul-01	11.2%	6.3
50	HCTZ/triamterene	b	25-37.5	-	cap	Geneva	Jun-97	0.0%	0.0
		L C							
	rugs, Average Weighted	•						6.0%	3.4
CPI - All II	tems less Energy, Annua	Perce	ent Chang	е				1.8%	

^a Based on price as of January 15 for each year reported. Drugs are listed in descending order of number of prescriptions.

^b Generic or co-marketed versions of this drug product are available.

^c The weighted average was calculated based on 2002 expenditures for each drug in the Pennsylvania PACE program.

Table 2
Cumulative Price Change of the Top 50 Drugs (by Number of Claims) Used by the Elderly^a

Rank by # of Claims	Drug Name		Streng	gth	Dose Form	Therapeutic Category	Cumulative Change 1998-2003	Multiple of CPI 1998-2003
1	Lipitor		10	mg	tab	Lipid-Lowering Agent	30.8%	2.6
2	Norvasc		5	mg	tab	Calcium Channel Blocker	16.5%	1.4
3	Fosamax		70	mg	tab	Osteoporosis Treatment	nm	nm
4	Plavix		75	mg	tab	Anti-Platelet Agent	nm	nm
5	Prilosec		20	mg	cap cr	Gastrointestinal Agents	22.5%	1.9
6	Celebrex		200	mg	cap	Anti-Inflammatory/Analgesic	nm	nm
7	furosemide	Ь	40	mg	tab	Loop Diuretic	135.2%	11.4
8	Zocor		20	mg	tab	Lipid-Lowering Agent	25.2%	2.1
9 10	Prevacid Norvasc		30	mg	cap cr	Gastrointestinal Agent	33.3%	2.8
11	Lipitor		10 20	mg	tab tab	Calcium Channel Blocker	0.0% 29.2%	2.5
12	Klor-Con M20	b	20	mg meq	tab cr	Lipid-Lowering Agent Potassium Replacement	29.2% nm	nm
13	Toprol XL	b	50	mg	tab cr	Beta Blocker	42.8%	3.6
14	Xalatan		0.005	%	sol	Glaucoma Treatment	34.8%	2.9
15	Vioxx		25	mg	tab	Anti-Inflammatory/Analgesic	nm	nm
16	Lanoxin	Ь	0.125	mg	tab	Cardiac Glycoside	36.6%	3.1
17	Synthroid	b	0.1	mg	tab	Synthetic Thyroid Agent	63.6%	5.4
18	Synthroid	b	0.05	mg	tab	Synthetic Thyroid Agent	63.8%	5.4
19	metoprolol tartrate	b	50	mg	tab	Beta Blocker	15.8%	1.3
20	isosorbide mononitrate	b	30	mg	tab cr	Anti-Anginal Agent	nm	nm
21	Digitek	b	0.125	mg	tab	Cardiac Glycoside	nm	nm
22	isosorbide mononitrate	b	60	mg	tab cr	Anti-Anginal Agent	nm	nm
23	metoprolol tartrate	b	50	mg	tab	Beta Blocker	20.3%	1. <i>7</i>
24	Synthroid	b	0.075	mg	tab	Synthetic Thyroid Agent	63.6%	5.4
25	Zoloft		50	mg	tab	Antidepressant	19.6%	1. <i>7</i>
26	Protonix		40	mg	tab	Gastrointestinal Agent	nm	nm
27	Cozaar		50	mg	tab	Angiotensin II Inhibitor	25.3%	2.1
28	atenolol	b	25	mg	tab	Beta Blocker	16.4%	1.4
29	Premarin		0.625	mg	tab	Estrogen Replacement	88.5%	7.5
30	furosemide	Ь	20	mg	tab	Loop Diuretic	136.4%	11.5
31	Zocor		40	mg	tab	Lipid-Lowering Agent	25.2%	2.1
32 33	Evista		60	mg	tab	Osteoporosis Treatment	23.9%	2.0
33	Nexium Zocor		40 10	mg	cap tab	Gastrointestinal Agent	nm 25.2%	<i>nm</i> 2.1
35	Combivent		10	mg mg	aerosol	Lipid-Lowering Agent Respiratory Agent	54.0%	4.6
36	Miacalcin		200	IU/act	spray	Calcitonin Replacement	43.6%	3.7
37	atenolol	b	50	mg	tab	Beta Blocker	12.8%	1.1
38	Pravachol	~	20	mg	tab	Lipid-Lowering Agent	49.4%	4.2
39	Paxil		20	mg	tab	Antidepressant	31.7%	2.7
40	Toprol XL		100	mg	tab cr	Beta Blocker	42.8%	3.6
41	Celexa		20	mg	tab	Antidepressant	nm	nm
42	hydrochlorothiazide	b	25	mg	tab	Thiazide Diuretic	360.5%	30.5
43	Glucotrol XL		10	mg	tab cr	Oral Antidiabetic Agent	27.2%	2.3
44	Klor-Con 10	b	10	meq	tab cr	Potassium Replacement	72.1%	6.1
45	furosemide	b	40	mg	tab	Loop Diuretic	123.7%	10.4
46	potassium chloride	b		meq	cap cr	Potassium Replacement	81.5%	6.9
47	Lanoxin	b	0.25	mg	tab	Cardiac Glycoside	36.6%	3.1
48	Claritin		10	mg	tab	Non-Sedating Antihistamine	51.2%	4.3
49	Diovan		80	mg	tab	Angiotensin II Inhibitor	nm	nm
50	HCTZ/triamterene	b	25-37.5	mg	cap	Potassium Replacement	0.0%	-
Top 50 Di	rugs, Average Weighted	by Sa	les ^c				29.2%	2.5
CFI - All II	iems less Lilergy, Amnua	rerce	in Change	-			11.8%	

 $\it nm$ $\,$ Not marketed during part or all of the period indicated.

^a Based on price as of January 15 for each year reported. Drugs are listed in descending order of number of prescriptions.

^b Generic or co-marketed versions of this drug product are available.

^c The weighted average was calculated based on 2002 expenditures for each drug in the Pennsylvania PACE program.

Table 3
Wholesale Cost Per Year of Therapy for Top 50 Drugs (by Number of Claims)
Used by the Elderly^a

Rank by # of Claims	Drug Name	Stre	ength		Dose Form	NDA Approval Date	Number of Price Changes 1998-2003		2003 st/Year
1	Lipitor		10	mg	tab	Dec-96	4	\$	871
2	Norvasc		5	mg	tab	Jul-92	5	\$	549
3	Fosamax		70	mg	tab	Sep-95	3	\$	894
4	Plavix		75	mg	tab	Nov-97	6	\$	1,539
5	Prilosec		20	mg	cap cr	Sep-89	5	\$	1,684
6	Celebrex		200	mg	cap	Dec-98	4	\$	2,102
7	furosemide	b	40	mg	tab	Aug-81	3	\$	59
8	Zocor		20	mg	tab	Dec-91	4	\$	1,674
9	Prevacid		30	mg	cap cr	May-95	7	\$	1,690
10	Norvasc		10	mg	tab	Jul-92	0	\$	794
11	Lipitor		20	mg	tab	Dec-96	5	\$	1,330
12	Klor-Con M20	b	20	meq	tab cr	Nov-98	2	\$	386
13	Toprol XL		50	mg	tab cr	Jan-92	8	\$	277
14	Xalatan		0.005	%	sol	Jun-96	5	\$	186
15	Vioxx		25	mg	tab	May-99	4	\$	1,050
16	Lanoxin	Ь	0.125	mg	tab	Sep-97	6	\$	88
17	Synthroid	Ь	0.1	mg	tab	Dec-63	10	\$	153
18	Synthroid	Ь	0.05	mg	tab	Dec-63	10	\$	136
19	metoprolol tartrate	b	50	mg	tab	Dec-93	2 1	\$ \$	405
20 21	isosorbide mononitrate	b b	0.125	mg	tab cr tab	Sep-98 Mar-95	4	\$	407 69
22	Digitek isosorbide mononitrate	Ь	60	mg	tab cr	Sep-98	1	\$ \$	429
23	metoprolol tartrate	Ь	50	mg mg	tab	Jan-95	1	\$	405
24	Synthroid	Ь	0.075	mg	tab	Dec-63	10	\$	150
25	Zoloft	D	50	mg	tab	Dec-91	5	\$	966
26	Protonix		40	mg	tab	Feb-00	4	\$	1,282
27	Cozgar		50	mg	tab	Apr-95	6	\$	553
28	atenolol	Ь	25	mg	tab	Sep-91	1	\$	298
29	Premarin		0.625	mg	tab	May-64	10	\$	324
30	furosemide	Ь	20	mg	tab	Aug-81	3	\$	52
31	Zocor		40	mg	tab	Dec-03	4	\$	1,674
32	Evista		60	mg	tab	Dec-97	6	\$	895
33	Nexium		40	mg	cap	Feb-01	3	\$	1,614
34	Zocor		10	mg	tab	Dec-91	5	\$	959
35	Combivent		1	mg	aerosol	Oct-96	9	\$	10,868
36	Miacalcin		200	IU/act	spray	Aug-95	7	\$	<i>7</i> ,132
37	atenolol	b	50	mg	tab	Sep-91	1	\$	304
38	Pravachol		20	mg	tab	Oct-91	6	\$	1,124
39	Paxil		20	mg	tab	Dec-92	6	\$	1,031
40	Toprol XL		100	mg	tab cr	Jan-92	8	\$	416
41	Celexa	,	20	mg	tab	Apr-00	7	\$	880
42	hydrochlorothiazide	Ь	25	mg	tab	Jun-98	4	\$	29
43	Glucotrol XL	,	10	mg	tab cr	Apr-94	6	\$	308
44	Klor-Con 10	b	10	meq	tab cr	Nov-98	3	\$	342
45	furosemide	Ь	40	mg	tab	Aug-81	2	\$	57
46	potassium chloride	Ь	10	meq	cap cr	Feb-87	4	\$	221
47 48	Lanoxin Claritin	Ь	0.25	mg	tab tab	Aug-6 <i>7</i> Apr-93	6 13	\$ \$	88 1,1 <i>7</i> 8
48	Diovan		80	mg		Jul-01	3	\$	567
50	HCTZ/triamterene	Ь	25-37.5	mg mg	tab	Jui-01 Jun-97	1	э \$	137
	•			ilig	cap	JUII-77			
· ·	rugs, Average Weighted	by Sc	lies				4.9	\$	1,439
Number on Market by Year 50									

nm Not marketed during part or all of the period indicated.

^a Based on price as of January 15 for each year reported. Drugs are listed in descending order of number of prescriptions.

^b Generic or co-marketed versions of this drug product are available.

^c The weighted average was calculated based on 2002 expenditures for each drug in the Pennsylvania PACE program.

Table 4
Price Change of the Top 50 Drugs (by Number of Claims) Used by the Elderly^a

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Rankby	Brand		Streng	gth	Dose	Therapeutic	Co	st/Year	Co	t/Year	
# of	Name				Form	Category		1997		2003	
Claims											
1	Lipitor		10	mg	tab	Lipid-Lowering Agent	\$	666	\$	871	
2	Norvasc			mg	tab	Calcium Channel Blocker	\$	459	\$	549	
3	Fosamax			mg	tab	Osteoporosis Treatment	•	nm	\$	894	
4	Plavix			mg	tab	Anti-Platelet Agent		nm	\$	1,539	
5	Prilosec			mg	cap cr	Gastrointestinal Agent	\$	1,325	\$	1,684	
6	Celebrex			mg	cap	Anti-Inflammatory/Analgesic	·	nm	\$	2,102	
7	furosemide	b		mg	tab	Loop Diuretic	\$	25	\$	59	
8	Zocor			mg	tab	Lipid-Lowering Agent	\$	1,292	\$	1,674	
9	Prevacid			mg	cap cr	Gastrointestinal Agent	\$	1,249	\$	1,690	
10	Norvasc			mg	tab	Calcium Channel Blocker	\$	794	\$	794	
11	Lipitor		20	mg	tab	Lipid-Lowering Agent	\$	1,029	\$	1,330	
12	Klor-Con M20	b	20	meq	tab cr	Potassium Replacement		nm	\$	386	
13	Toprol XL		50	mg	tab cr	Beta Blocker	\$	185	\$	277	
14	Xalatan		0.005	%	sol	Glaucoma Treatment	\$	132	\$	186	
15	Vioxx		25	mg	tab	Anti-Inflammatory/Analgesic		nm	\$	1,050	
16	Lanoxin	b	0.125	mg	tab	Cardiac Glycoside	\$	51	\$	88	
1 <i>7</i>	Synthroid	b	0.1	mg	tab	Synthetic Thyroid Agent	\$	86	\$	153	
18	Synthroid	b	0.05	mg	tab	Synthetic Thyroid Agent	\$	76	\$	136	
19	metoprolol tartrate	b	50	mg	tab	Beta Blocker	\$	350	\$	405	
20	isosorbide mononitrate	b		mg	tab cr	Anti-Anginal Agent		nm	\$	407	
21	Digitek	b	0.125	mg	tab	Cardiac Glycoside		nm	\$	69	
22	isosorbide mononitrate	b		mg	tab cr	Anti-Anginal Agent		nm	\$	429	
23	metoprolol tartrate	Ь		mg	tab	Beta Blocker	\$	337	\$	405	
24	Synthroid	b		mg	tab	Synthetic Thyroid Agent	\$	84	\$	150	
25	Zoloft			mg	tab	Antidepressant	\$	787	\$	966	
26	Protonix			mg	tab	Gastrointestinal Agent	*	nm	\$	1,282	
27	Cozaar			mg	tab	Angiotensin II Inhibitor	\$	416	\$	553	
28	atenolol	b		mg	tab	Beta Blocker	\$	256	\$	298	
29	Premarin	ı.		mg	tab	Estrogen Replacement	\$	165	\$	324	
30	furosemide	Ь		mg	tab	Loop Diuretic	\$	22	\$	52	
31 32	Zocor Evista			mg	tab ***	Lipid-Lowering Agent	\$	1,342	\$ \$	1,674 895	
33	Nexium			mg	tab	Osteoporosis Treatment		nm	\$	1,614	
34	Zocor			mg	cap tab	Gastrointestinal Agent Lipid-Lowering Agent	\$	nm 741	\$	959	
35	Combivent			mg mg	aerosol	Respiratory Agent	\$	7,056	\$	10,868	
36	Miacalcin		•	IU/act	spray	Calcitonin Replacement	\$	4,568	\$	7,132	
37	atenolol	Ь		mg	tab	Beta Blocker	\$	270	\$	304	
38	Pravachol	5		mg	tab	Lipid-Lowering Agent	\$	717	\$	1,124	
39	Paxil			mg	tab	Antidepressant	\$	753	\$	1,031	
40	Toprol XL			mg	tab cr	Beta Blocker	\$	277	\$	416	
41	Celexa			mg	tab	Antidepressant	_	nm	\$	880	
42	hydrochlorothiazide	b		mg	tab	Thiazide Diuretic	\$	6	\$	29	
43	Glucotrol XL			mg	tab cr	Oral Antidiabetic Agent	\$	236	\$	308	
44	Klor-Con 10	b	10		tab cr	Potassium Replacement	\$	186	\$	342	
45	furosemide	b	40		tab	Loop Diuretic	\$	25	\$	57	
46	potassium chloride	b	10	-	cap cr	Potassium Replacement	\$	122	\$	221	
47	Lanoxin	b		mg .	tab	Cardiac Glycoside	\$	51	\$	88	
48	Claritin			mg	tab	Non-Sedating Antihistamine	\$	760	\$	1,1 <i>7</i> 8	
49	Diovan		80	mg	tab	Angiotensin II Inhibitor		nm	\$	567	
50	HCTZ/triamterene	b	25-37.5	mg	cap	Potassium Replacement		nm	\$	13 <i>7</i>	
									,		
Top 50 Di	rugs, Average Weighted	by Sc	iles				\$	1,116	\$	1,439	
Number of	on Market by Year							36		50	

nm Not marketed during part or all of the period indicated.

^a Based on price as of January 15 for each year and usual dose as reported in PriceChek PC. Drugs are listed in descending order of expenditures.

^b Generic or co-marketed versions of this drug product are available.

^c The weighted average was calculated based on 2002 expenditures for each drug in the Pennsylvania PACE program.

METHODOLOGY

This report used data from the Pennsylvania Pharmaceutical Assistance Contract for the Elderly (PACE) program, which is the largest outpatient prescription drug program for older Americans in the United States. In 2002, 268,005 people were enrolled in the PACE program, and PACE filled 9,144,923 prescriptions. Because of its large size and the abundance of claims data, the PACE database is commonly used to estimate prescription drug use and expenditures by older Americans.

Using PACE claims for 2002 (the latest claims data available), we developed a list of the 50 top-selling prescription drugs used by senior citizens—individuals 65 and over in the PACE program—and ranked them by number of prescriptions issued. Price histories for the 50 top-selling drugs in the PACE program were obtained from PriceChek PC, a database published by Medispan/First DataBank. The price indicator used in this report is the average wholesale price (AWP)—the price that drug marketers suggest wholesalers charge pharmacies.

Some people suggest that AWP is not an accurate measure of drug prices paid by consumers because so many consumers enjoy discounts negotiated by managed care organizations or other bulk purchasers of pharmaceuticals. Because significant numbers of the elderly have no prescription drug coverage, however, this is not an option for a large portion of older Americans.

This report uses weighted averages in calculating annual price increases for the entire list of top-selling prescription drugs. In other words, before averaging, the price of each drug is multiplied by a factor representing the drug's percentage of total sales of all drugs on the list for a given year. This adjustment is made to ensure that price trends accurately reflect the cost of drugs older people use most often.

DISCUSSION

Rising drug prices present a hardship to all consumers, but they are especially difficult for older Americans. Although seniors comprise just 13 percent of the population, they consume over one-third of all prescription drugs used in the U.S. and account for 42 cents of every dollar spent on prescription drugs. Among Medicare beneficiaries, 90 percent use prescription drugs during the course of a year, and they pay an average of \$2,322 a year for them. And their use of prescription drugs is expected to increase. The Congressional Budget Office projects that total drug spending for the Medicare population will grow from an estimated \$95 billion in 2003 to \$284 billion in 2013. This translates to an estimated increase of 10 percent annually.

At the same time that seniors are using prescription drugs more, major sources of coverage available to them are shrinking. Employer-sponsored retiree health plans have been the leading source of drug coverage for seniors, filling the gap left by Medicare's lack of a drug benefit for approximately one-third of those in Medicare. However, retiree health plans have been eliminating or reducing drug coverage. In 2001, only a third of employers with over 200 employees offered health care coverage to those over 65. Retirees cannot rely with any certainty on employer coverage in the future. Twenty-two percent of large employers say they are likely to terminate health benefits for future retirees, and 85 percent report that they are likely to reduce prescription drug benefits. As employer coverage for retirees withers, the seniors who once could rely on those plans will be more directly affected by the upward spiral in drug prices.

Price Increases and Those with No Coverage Options

While employer plans have provided some coverage for many in Medicare, they have not been a real option for low-income seniors. Only 14 percent of seniors with incomes under 200 percent of poverty are estimated to have drug coverage through an employer-sponsored plan, compared to 42 percent of those with incomes over 200 percent of poverty.¹²

It is not just employer-sponsored plans that fail to reach low-income seniors. Medicaid, which provides prescription drug coverage to many low-income individuals, misses millions of low-income seniors. Only 27 percent of those in Medicare with incomes under 200 percent of poverty are covered by the Medicaid program; only 11 percent have Medicaid coverage for a full year.¹³

Over a third of the nearly 18 million Medicare beneficiaries with incomes under 200 percent of poverty—less than \$17,960 per year for an individual in 2003—do not have any source of prescription drug coverage. They must pay for the medications that they need out of their own funds. On average, they pay approximately \$1,135 out-of-pocket for prescription drugs annually, which comes to over 6 percent of total annual income for an individual whose income is 200 percent of poverty. Their average out-of-pocket spending is lower than the overall per capita beneficiary drug spending because they cannot afford to purchase all of the drugs they need. Low-income Medicare beneficiaries without drug coverage fill an average of 21 prescriptions a year, while their counterparts with coverage fill, on average, 31. For low-income seniors without drug coverage, increases in drug prices well above general inflation and their fixed real incomes often mean that some essential medications will go unfilled.

Real Health Consequences of Rising Drug Prices

Of the 27 drugs that increased in price three or more times the rate of inflation, 15 are used for the treatment of high-blood pressure or heart conditions. Most of the remaining are for the treatment of other serious chronic conditions such as osteoporosis, diabetes, chronic respiratory ailments, or glaucoma. These are essential medications that seniors depend on for their health and well-being.

Fast-rising drug prices are placing essential medications out of seniors' financial reach. In 2001, nearly one in four seniors reported that they skipped doses or did not fill medications due to costs.¹⁷ Numerous studies have shown that lack of coverage causes individuals, particularly low-income individuals, to go without medications needed to treat serious conditions, such as hypertension.¹⁸ If drug prices continue to rise faster than inflation, the number of seniors without adequate coverage who skip medications will undoubtedly increase.

Generic Drugs Provide Some Relief

Generic drugs can provide a measure of relief from the upward price spiral. The prices of generic drugs rose more slowly last year than those of brand-name drugs. In January 2003, among the drugs most frequently used by seniors, the annual average cost of generics was 76 percent less than the average annual cost of the brand-name drugs most frequently used by seniors. Aside from huge differences in annual costs, generic drugs did not have the same price increases as did the brand-name drugs most frequently used by seniors: a 2.6 percent annual price increase from 2002 to 2003 for generics versus 7.1 percent for brand-name drugs. Generics comprised over three-quarters of the drugs frequently used by seniors that did not increase in price.

Yet only 30 percent of the drugs most frequently used by seniors were generics. There are reasons that generics did not represent a greater percentage of these drugs: Brand-name drug manufacturers' efforts to keep generics off the market and their heavy promotion of high-cost brand-name drugs fuel use of those drugs.

■ *Keeping Generics Off the Market:* Generics mean price competition and large savings to consumers and other health care purchasers. Studies have shown that a generic prescription is about half the price of a prescription for the brand-name counterpart.¹⁹ The availability of lower-priced generics can mean billions of dollars in savings to consumers, governments, and other drug purchasers.²⁰ For brand-name drug manufacturers, this price competition translates into lost market share and lost revenue.²¹

A brand-name drug manufacturer can make billions of dollars off the sale of a so-called "blockbuster" drug. In 2002, Pfizer recorded \$7.97 billion in revenue from sales of Lipitor, the drug most frequently prescribed to seniors; its revenue from Norvasc, the second most frequently prescribed drug, was \$3.85 billion.²² Sales of Fosamax, the third most frequently prescribed drug for seniors, provided Merck with \$2.2 billion in revenue in 2002.²³

With revenues at that level, it is no surprise that brand-name drug manufacturers have gone to great lengths to keep generics off the market. For example, they have played games with patent extensions by listing frivolous or improper patents with the Food and Drug Administration (FDA). This has had the effect of keeping generics off the market, sometimes for years, and at significant cost to consumers. For example, Bristol-Myers Squibb obtained a patent for the chemical produced in the body after a patient takes BuSpar, an anti-anxiety medication the company manufactures. By improperly listing that patent with the FDA, Bristol-Myers Squibb was able to delay generic competition for months.

The BuSpar example is not a lone case. In 2002, the Federal Trade Commission (FTC) issued a report on generic drug market entry, focusing in large part on brand-name manufacturers' use of improper patents to keep generics off the market. The report looked at 104 applications for generic drug approvals, each involving a generic manufacturer challenging a brand-name manufacturers' patent—usually contending the patent was improper or invalid. In 75 cases, the brand-name manufacturer sued the generic company to keep the generic drug off of the market. As an indication of whether these brand-name drug patents were valid or were just ways to delay generic competition, it is noteworthy that, in the cases in which a court decision had been reached at the time the report was published, the generic manufacturer had prevailed 73 percent of the time.²⁵

Although there have been recent regulatory changes surrounding the types of patents that drug manufacturers may and may not list with the FDA, there remains room for brand-name manufacturers to delay consumers' access to generics. Given the significant savings that generics can provide to all health care purchasers—from consumers to the government—every effort should be taken so that legislation ensures that generics are available to consumers without delays. (See text box, "The Games Drug Companies Play: Why the Recent FDA Rule Is Not Enough.")

■ Generating Demand by Promoting High-Cost Drugs: In addition to trying to squelch generic competition, the pharmaceutical industry has successfully used marketing to physicians and consumers to generate demand. While providing physicians and consumers with balanced, correct information on new products is important, advertising has been disproportionately focused on newer, higher-priced products and linked to an explosion of the use of those products.

Direct mass-media marketing of prescription drugs was approved in 1997. Since then, the industry has poured billions of dollars into advertising. In 2001 alone, Pfizer reported that it spent nearly \$2.9 billion on advertising; Bristol-Myers Squibb reported spending over \$1.4 billion on "advertising and promotion." Companies spend these sums on advertising because it works: Pfizer increased direct-to-consumer advertising for Lipitor, the most frequently prescribed drug for seniors, sixfold between 1998 and 1999 and saw the number of prescriptions increase by 50 percent. Property of the property of the prescriptions increase by 50 percent.

Direct-to-consumer advertising is just a part of industry marketing. Drug companies also spend huge sums promoting their products directly to physicians and the companies that manage drug benefits. Sales force size in major drug companies indicates the importance of direct promotion to physicians. It is estimated that, in 2001, over 80,000 people were employed as drug sales representatives.²⁸ Overall, the industry employed 81 percent more people in marketing than in research.²⁹

Industry spending patterns undercut its argument that high drug prices are needed to fund research and development (R&D). In 2001, the manufacturers of the 50 drugs most frequently prescribed to seniors spent nearly two-and-a-half times more on marketing, advertising and administration than they did on research and development.³⁰

CONCLUSION

As seniors continue to wait for a drug benefit in Medicare, they are experiencing drug prices that, year after year, increase well in excess of the rate of inflation. From January 2002 to January 2003, the increase was nearly three-and-a-half times the rate of inflation. For seniors on fixed incomes with no drug coverage, increases at that level make it impossible to continue purchasing the medications they need. For low-income seniors, rising drug prices too often mean that necessary medications go unfilled. The result: greater emergency room and hospital use and higher overall costs to the health care system.³¹

The rise in the price of drugs most frequently used by seniors from January 2002 to January 2003 highlights, for yet another year, the need for a prescription drug benefit in Medicare. The stark difference in prices among the top 50 drugs also points to the need for strong measures to ensure that consumers have timely access to generic drugs. With expanded coverage and access to generics, broader strategies for price moderation must also be considered. Without moderation in drug prices, employers, governments, and other health care payers will cut back on coverage and pass costs on to consumers—costs that consumers will not be able to bear.

The Games Drug Companies Play: Why the Recent FDA Rule Is Not Enough

In June 2003, the FDA released new rules intended to improve consumers' access to generic drugs and curb the abuses such as those described in this report surrounding Bristol-Myers Squibb's delay of a generic version of BuSpar. The FDA's rule closes some loopholes in the law, a law that is very complex and convoluted. But the rule does not go far enough. Stronger measures, such as legislative fixes, are needed to ensure that consumers have timely access to generics.

▶ The way patents and generic approvals work: a basic overview

Brand-name drug manufacturers list their drug patents with the FDA. It is this patent listing the FDA uses to determine whether a generic can be approved for marketing. Although only certain types of patents are supposed to be listed, the FDA does not review the patents drug manufacturers submit. Generic manufacturers cannot preemptively challenge the patents brand manufacturers list as being improper or frivolous. Generic manufacturers can, however, submit an application for generic drug approval even if there is an unexpired patent on the brand drug; with that application, it has to "certify" that the brand-name manufacturer's patent is invalid or will not be infringed by the generic. The generic manufacturer also has to notify the brand manufacturer of the patent challenge. This notification gives the brand manufacturer a right to sue to stop the generic from coming to market. The first generic manufacturer to be approved by the FDA in connection with a patent challenge has six months (180 days) of market exclusivity; during that time, no other generic drug can come to market.

▶ How the system has been gamed before the FDA rule

Prior to the FDA rule, once a generic manufacturer challenged a brand-name drug patent, the brand manufacturer had 45 days to sue; if it did, approval of the generic was automatically delayed for the lesser of two-and-a-half years or until the resolution of the lawsuit. If it did not sue in the allotted time, the generic drug approval moved forward. There was no limit on the number of times that a brand manufacturer could use the two-and-a-half year delay tactic. As a result, brand manufacturers patented all sorts of drug attributes—the tablet size and shape, the drug's interaction in the body, even the packaging. Each new patent could be used to delay generic competition.

Beyond gaming patent listings, in some cases, brand manufacturers have made deals with generic manufacturers to "sit on" the six-month market exclusivity. Because the six-month clock does not start to run until the first generic is on the market, a generic manufacturer that delays bringing its drug to market can create a bottleneck for all other generics.

▶ What the new FDA rule does and doesn't do

The June 2003 FDA rule clarifies the types of patents that brand manufacturers can list. Many of the types of patents that have been used to delay generics are now clearly improper. However, the FDA still does not review patents, and improper patents will likely still be listed and used to delay generics. Under the FDA rule, brand-name drug manufacturers can only use the two-and-a-half year delay one time. However, there is no requirement for the brand company to file a lawsuit within a set period of time. This means that generic manufacturers could be sued up until, and even after, they start to market the generic; after marketing begins, damages are tripled for a company that violates a patent. Generic manufacturers may decide that it is better to simply stay off the market until all patents expire, even if the patents are improper. Finally, the rules do not require that generic manufacturers "use or lose" the six-month market exclusivity, still leaving the door open for a generic manufacturer to block subsequent generics from market.

▶ What needs to be done

Stronger measures are needed to make sure that drug manufacturers cannot continue to game the system and delay consumers' access to lower-cost generic drugs. These measures should close the opportunities for abuse not addressed in the FDA rule, such as requiring that any generic with six-month market exclusivity either bring a product to market in a timely manner or lose that exclusivity. The system should support speedy generic approval, prompt and complete resolution of any patent issues, and greater involvement of the FDA to ensure that improper patents are not filed. When it comes to giving consumers access to generics, a lot is at stake: billions of dollars in lost profits for brandname drug manufacturers and billions of dollars in savings for consumers and other health care payers. With so much at stake, the drug industry will remain creative in its efforts to delay generics. The legislation and regulations that govern generic approval should close off opportunities for abuse.

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